

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Oral Argument Requested

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO  
PLAINTIFFS' *DAUBERT* MOTION TO PRECLUDE  
DEFENSE EXPERT WILLIAM J. LAMBERT, PH.D.,  
FROM OFFERING CLASS CERTIFICATION OPINIONS**

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Pursuant to Federal Rules of Evidence 104, 403, and 702, Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, “Aurobindo”) submit this memorandum of law in opposition to Plaintiffs’ *Daubert* Motion to Preclude Defense Expert William J. Lambert, Ph.D. from Offering Class Certification Opinions (the “Motion”), ECF 2044, and state as follows:

## **I. INTRODUCTION**

Plaintiffs’ Motion is an improper attempt to test the accuracy of an expert’s conclusions instead of the sufficiency of an expert’s applied methodology. Assessment of an expert’s conclusions is for the trier of fact, guided by appropriate cross-examination. Here, Plaintiffs do not challenge Dr. Lambert’s methodology. Instead, they press two narrow complaints about his report as a purported basis to seek exclusion of his opinions *in their entirety*. Plaintiffs’ complaints are without merit. And, even if they were right, neither point would be a basis to exclude Dr. Lambert’s opinions altogether.

**First**, Plaintiffs erect a straw man argument and then tear it down, erroneously asserting that “despite being purportedly offered to opine on [REDACTED], Dr. Lambert actually *has no opinions on the matter at all.*” Mot., 1. Dr. Lambert did not offer a specific opinion as to whether “Aurobindo complied with cGMPs” nor was he required to do so.

Rather, Dr. Lambert opined regarding scope, assessment, and application of cGMPs to the matters at hand. Plaintiffs’ circular reasoning falls flat and completely ignores the opinions Dr. Lambert did offer. It provides no basis for exclusion of Dr. Lambert’s opinions.

*Second*, Plaintiffs seek to exclude Dr. Lambert because of allegedly “unsupported” opinions concerning the value of Aurobindo’s product, while ignoring the clear basis Dr. Lambert provided to support those opinions—*i.e.*, their unchanged bioequivalence to the reference listed drugs. Willful ignorance of opinions presented cannot support the Motion.

Dr. Lambert’s well-supported opinions were produced by a reliable methodology applying the expert’s specialized knowledge to the facts before him and, as such, they must necessarily survive this Motion for proper presentation to a jury to aid in understanding the issues presented in this case. Plaintiffs’ Motion should be denied.

## II. LEGAL STANDARD<sup>1</sup>

During *Daubert* proceedings to date, the Court has explained that [REDACTED]

[REDACTED]

[REDACTED]

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<sup>1</sup> For a complete recitation of the applicable legal standard, see Defendants’ oppositions to Plaintiffs’ *Daubert* motions filed at ECF 1786, 1787, 1788, 1791, and 1796. Those standards are incorporated herein by reference.

[REDACTED] Its determination at this stage concerns [REDACTED]

[REDACTED] In other words, the Court [REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

### **III. DR. LAMBERT'S EXPERT QUALIFICATIONS AND EXPERT OPINIONS**

Dr. Lambert is qualified to opine on matters concerning cGMP and Chemistry, Manufacturing, and Controls ("CMC"). In addition to earning a B.S. in Pharmacy and a Ph.D. in Pharmaceutics, Dr. Lambert has worked in the industry for 35 years. *See* Ex. 1, Lambert Rpt. ¶¶ 5-14; Ex. 2, Lambert Tr. 30:20-32:7. Dr. Lambert has direct and extensive knowledge of and involvement with manufacturing cleaning procedures and cGMPs. *See* Ex. 1, Lambert Rpt. ¶¶ 5-14; Ex. 2, Lambert Tr. 30:20-32:7. Across a variety of roles, he has been responsible for a cGMP manufacturing facility that passed FDA inspection, hosting cGMP audits, and all CMC aspects for

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<sup>2</sup> Exhibits 1-5 reference the exhibits that Plaintiffs filed with the Motion on May 3, 2022. Exhibit 6 is attached to the Declaration of John P. Lavelle, Jr. submitted herewith.

drugs from development through manufacturing. *See id.* Dr. Lambert is presently a Pharmaceutical Development, CMC, cGMP, and Drug Delivery Consultant at Module 3 Pharmaceutical Consulting, a company he founded in 2018. Ex. 1, Lambert Rpt. ¶ 12. Plaintiffs' counsel has agreed that Dr. Lambert's training and experience qualify him as an expert in cGMP and CMC. *See* Ex. 2, Lambert Tr. 29:12-18; 108:8-10.

Based on his expertise, Dr. Lambert offered several relevant and reliable opinions to assist the trier of fact in this matter. With respect to Aurobindo (and, thus, not with respect to all potential class members), Dr. Lambert rendered several opinions, including that:

- **Aurobindo's VCDs were not worthless.** They met the USP compendial standards and FDA-approved specifications in the abbreviated new drug application, were approved AB generics in the FDA's Orange Book, and were bioequivalent to the reference listed drugs—meaning they performed their intended purpose giving them worth. The presence of nitrosamines did not change that bioequivalence and, thus, their worth. *See* Ex. 1, Lambert Rpt. ¶¶ 17(i)-(iii), 19, 31, 128.
- **Aurobindo had no reason to test for nitrosamines until their unexpected presence became known.** At that time, Aurobindo appropriately and reasonably investigated the presence of nitrosamines in its API and VCDs, which showed [REDACTED]. *See* Ex. 1, Lambert Rpt. ¶¶ 17(iv)-(vi), 131-32.
- **Aurobindo reasonably qualified and oversaw Lantech, its recovered solvent vendor.** *See* Ex. 1, Lambert Rpt. ¶¶ 17(viii)-(ix), 134-37.

- **Not all cGMP compliance observations by FDA are valid, and an FDA observation does not constitute a final agency determination that any condition is in violation of federal law.** The cGMP compliance issues observed by the FDA and related to the manufacture of VCDs are not the types of compliance issues that would impact all Defendants' VCDs equally due to manufacturer independence and differing systems, facilities, equipment, personnel, vendors, processes, and procedures. *See* Ex. 1, Lambert Rpt. ¶¶ 17(xi), 127.

#### IV. ARGUMENT

##### A. **Plaintiffs' Argument About Dr. Lambert's cGMP-Related Opinions is Incorrect and Does Not Preclude Dr. Lambert's Testimony.**

Plaintiffs do not challenge Dr. Lambert's numerous opinions regarding cGMPs, all properly reached through a reliable methodology. *See* Ex. 1, Lambert Rpt. ¶¶ 17(iv)-(xi), 127, 132, 134-37. Instead, they crafted a specific opinion that Dr. Lambert did *not* give—"Aurobindo was in compliance with cGMPs"—and assert that failure to give that one opinion<sup>3</sup> means that Dr. Lambert should not be allowed to say anything at all. *See* Mot., 1, 4-5.

Plaintiffs' request exceeds the scope of the Court's gatekeeping function. As the Third Circuit has directed, expert testimony should only be excluded when the expert's methodology is so flawed that the expert "lacks 'good grounds' for his or her conclusions." *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (3d Cir.

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<sup>3</sup> Such a broad opinion, unlimited in time and silent as to the Aurobindo entity and/or facility in question, is not warranted in this matter.

1994). Here, Dr. Lambert applied his cGMP expertise to render numerous sound opinions, which have not been challenged. He followed a reliable methodology and there is no basis to exclude his opinions concerning cGMPs.

Dr. Lambert used his knowledge of cGMPs, which broadly provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities, to render expert opinions in this matter. *See* Ex. 2, Lambert Tr. 87:5; Ex. 1, Lambert Rpt. ¶ 26; *see* Ex. 2, Lambert Tr. 123:10-16, 126:23-127:3; 128:5-9. He applied his expertise to study, analyze, and then opine on the role of cGMPs in the industry, FDA's authority to determine compliance status, the import of FDA Form 483s, the connection between cGMPs and adulteration, and certain of Aurobindo's specific manufacturing processes concerning impurity testing and recovered solvents. *See supra* Section III; Ex. 1, Lambert Rpt. ¶¶ 17(iv)-(xi), 127, 132, 134-37; Ex. 2, Lambert Tr. 36:2-37:1; 41:24-43:5; 93:7-14; 222:17-223:19. In the end, he concluded that Aurobindo reasonably qualified and oversaw recovered solvents vendor Lantech, appropriately assessed risk for nitrosamines, completely investigated its VCDs for nitrosamines, and voluntarily conducted the necessary recalls in coordination with FDA. *See* Ex. 1, Lambert Rpt. ¶¶ 17(iv), 17(vi), 17(ix), 70, 75, 96-97, 107, 114, 132.

As part of his work, Dr. Lambert necessarily analyzed the arguments and expert opinions put forward by the Plaintiffs in support of their motions for class

certification. He disagreed with many of their arguments and conclusions. But his analysis did not end there. As evident on the face of Dr. Lambert's report, he specified a conclusion one of Plaintiffs' experts asserted, explained why he disagreed, and stated his contrary opinion. *See* Ex. 1, Lambert Rpt. ¶¶ 34-38, 39, 40-48, 86-88, 89-91, 92-94, 95-98, 99-102, 103-05, 106-14, 115-17, 118-19, 120-25, 126. This approach is not simply disagreeing with an opposing expert and asserting that the opposite must be true, as Plaintiffs suggest. *See* Mot., 6, 7 n.7; Ex. 3, 3/2/2022 Tr. 162:6-8. It is a substantive disagreement between experts that is to be expected in a matter of this nature, and such a disagreement is solidly insufficient grounds for the exclusion of expert testimony. *See, e.g., In re Gabapentin Pat. Litig.*, MDL Dkt. No. 1384, 2011 WL 12516763, at \*10 (D.N.J. Apr. 8, 2011) (concluding that disagreement between experts regarding application of a methodology presents "a battle of the experts" to be resolved by the trier of fact).

Plaintiffs' straw man argument in no way undermines the methodology that Dr. Lambert followed in reaching the opinions he did present. Thus, the Motion must be denied.

**B. Plaintiffs' Argument Ignores Dr. Lambert's Stated Basis for VCD Value and Does Not Preclude Dr. Lambert's Testimony.**

A threshold component of Plaintiffs' damages case is their assertion that [REDACTED]. Plaintiffs so desperately need this to be true that they ignore and reject all information to the contrary. To

avoid Dr. Lambert's opinion that Aurobindo's VCDs had value, Plaintiffs conflate price and value, incorrectly attribute an improper economic opinion to Dr. Lambert, and attempt to undermine Dr. Lambert's opinion by calling it "tentative." These attempts fail.

Price and value are not interchangeable concepts. *See* Defs.' Mot. to Exclude Dr. Conti, ECF 2040-1, 8-16 (explaining why price and value are not interchangeable concepts). Dr. Lambert has not offered an economic opinion. To the contrary, he acknowledged that he is not an economist and made clear that he based his assignment of worth in Aurobindo's VCDs on his training and expertise. Ex. 2, Lambert Tr. 234:13-23. And his opinion of Aurobindo's VCDs' worth is not "tentative." Mot., 9.<sup>4</sup> It is clearly asserted and fully supported.

Based on his cGMP and CMC expertise, Dr. Lambert opined that the "Aurobindo VCDs, including those with trace nitrosamine, were bioequivalent to the reference listed drug (RLD)." Ex. 1, Lambert Rpt. ¶ 31. He analyzed the record and concluded that "[t]here is no evidence to the contrary." *Id.* He further opined that "these products were and are AB approved generics" in FDA's Orange Book. *Id.* He reasoned this status means that Aurobindo's VCDs "were bioequivalent and

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<sup>4</sup> Plaintiffs misrepresent Dr. Lambert's testimony when he stated: "So I don't believe I've offered any opinion on these topics." Mot., 9 (citing Ex. 2, Lambert Tr. 106:3-5). Dr. Lambert's answer was in response to a question about a legal interpretation of statutory language in 21 U.S.C. § 331. *See* Ex. 2, Lambert Tr. 105:10-24.

[] match[ed] the label and package insert,” they “satisf[ied] the criteria to be accurately described as generic equivalents,” and—most importantly—“***[t]hey could perform their intended purpose and were not worthless.***” *Id.* (emphasis added); *see* Ex. 1, Lambert Rpt. ¶¶ 17(iii), 42; Ex 2., Lambert Tr. 205:1-206:14, 209:17-210:1, 213:16-22, 240:11-21, 241:20-242:2. Dr. Lambert explained his bioequivalence assessment and the reasons why the bioequivalence assessments from Plaintiffs’ experts are wrong, including by explaining how “[t]here is no credible mechanism for nitrosamines to affect bioequivalence,” especially with the trace levels of nitrosamine found in certain Aurobindo lots. Ex. 1, Lambert Rpt. ¶ 42; *see id.* ¶¶ 30-31, 40-42, 47, 116.

Plaintiffs chose to barely address these opinions at Dr. Lambert’s deposition. In fact, the testimony that Plaintiffs cite in an attempt to undermine Dr. Lambert’s opinions actually provides further support. *See* Mot., 11 & n.16 (citing Ex. 2, Lambert Tr. 234:5-236:5). There, Dr. Lambert made clear that he used his “expertise” and “training” to assign worth to Aurobindo’s VCDs based on their “retained therapeutic or clinical value.” Ex. 2, Lambert Tr. 234:5-23; *see id.* 233:17-234:3 (“They probably prevented some myocardial infarctions. So yeah, I think they had value.”).

Further, Dr. Lambert’s report explains that Plaintiffs’ focus on technical adulteration under the statutory definition is misplaced and does not make

Aurobindo's VCDs worthless. FDA's *Facts About the Current Good Manufacturing Practices (CGMPs)* clearly states that:

“If a company is not complying with CGMP regulations, any drug it makes is considered ‘adulterated’ under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with CGMP. ***It does not mean that there is necessarily something wrong with the drug.***”

See Ex. 1, Lambert Rpt. ¶ 26; <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps> (emphasis added). FDA acted on this guidance with respect to Aurobindo's VCDs, advising that “[h]ealth care professionals should continue to prescribe medications when clinically appropriate even though they may have low levels of nitrosamine impurities.” See Ex. 1, Lambert Rpt. ¶ 25; FDA, *Information about Nitrosamine Impurities in Medication*, <https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications>.

Contrary to Plaintiffs' assertions, Dr. Lambert's agreement with counsel's recitation of 21 U.S.C. § 331(a)'s prohibition against introduction of an “adulterated” drug into interstate commerce does not render his opinions inadmissible. See Mot., 9 (citing Ex. 2, Lambert Tr. 104:10-105:8). FDA's own guidance shows that technically “adulterated” products can retain value and worth. The weight of authority supports Dr. Lambert as well. See *Shahinian v. Kimberly-Clark Corp.*, No. CV 14-8390-DMG (PLAx), 2017 WL 11595343, at \*11 (C.D. Cal.

Mar. 7, 2017) (excluding expert opinions premised on simplistic insistence that “adulterated or misbranded products [necessarily] have no value as a matter of law”); *Ctr. City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321 F.R.D. 193, 204 (E.D. Pa. 2017) (excluding damages expert for presuming dental device was “worthless” and failing to credit “value obtained even with the alleged defect”); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (treating recalled diabetes drug as “worthless. . . . is not a defensible position” because medication was “beneficial to many patients”); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 213 (D. Minn. 2003) (the court “cannot accept” that recalled medication “did not provide any benefit” where there was no dispute that it “effectively reduce[d] cholesterol”).

Plaintiffs’ supplemental arguments also ring hollow. **First**, Plaintiffs complain that Dr. Lambert “does not quantify or posit [REDACTED] might have had or explain how or why he gets to that rumination.” Mot., 9. But Dr. Lambert is not required to specify an exact value—Plaintiffs can cite no authority requiring it—and not doing so is not grounds for excluding his opinions. **Second**, Plaintiffs assert that “the undisputed evidence—which Dr. Lambert ignored in preparing his report, but which he admitted to at deposition—shows [REDACTED] [REDACTED].” Mot., 9. Yet, they cite no documents or deposition testimony in support; this claim is unsubstantiated. **Third**, they attribute

a “concession” to Dr. Lambert that is not supported by his testimony,<sup>5</sup> and fail to state how such a “concession” means that Aurobindo’s VCDs were worthless. Mot., 11.

*Finally*, Plaintiffs incorrectly state that Dr. Lambert did not know and did not consider that [REDACTED]. Mot., 11 & n.14.<sup>6</sup> As conveyed in his report and his deposition, he knew and considered that Aurobindo recalled some, but not all, VCDs. *See* Ex. 1, Lambert Rpt. ¶¶ 17(iv) ([REDACTED]), 23 (same); Ex. 2, Lambert Tr. 168:6-9 [REDACTED].

Plaintiffs, again, are plainly wrong.

Each alleged deficiency in Dr. Lambert’s opinions is refuted on the face of Dr. Lambert’s report, and none undermine the methodology he used to reach his opinions. There is no basis for exclusion.

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<sup>5</sup> Plaintiffs state that Dr. Lambert “conceded that if given the choice [REDACTED].” Mot., 11. Dr. Lambert actually stated: “So I suppose, given the choice, yeah, you might choose the uncontaminated.” Ex. 2, Lambert Tr. 256:17-19. In the remainder of his answer, which Plaintiffs excluded from the Motion, he states: “But the issue is, is there would have been a drug shortage. And so the supply of valsartan would not have been sufficient to meet the demand.” Ex. 2, Lambert Tr. 256:20-23.

<sup>6</sup> Plaintiffs cite Ex. 2, Lambert Tr. 255:4-20, which concerns VCDs from manufacturers other than Aurobindo, and Dr. Lambert expressed no opinions on non-Aurobindo VCDs.

**C. Plaintiffs’ Mischaracterization of Witness Testimony Does Not Preclude Dr. Lambert’s Opinions.**

Because Dr. Lambert’s opinions followed an appropriate methodology and were based on record evidence, Plaintiffs’ Motion should be denied without need for the Court even to consider Plaintiffs’ attempts to undermine Dr. Lambert’s opinions based on purported contrary evidence. Should the Court consider Plaintiffs’ arguments, their assertions are incorrect and take the testimony they rely on out of context.

*First*, Plaintiffs state that Ms. Johns, in her role as “Aurobindo’s own Rule 30(b)(6) designee on regulatory issues and Director of Regulatory Affairs” “testified that [REDACTED].” Mot., 10. That is a misrepresentation of Ms. John’s testimony. After establishing that she was not aware that plaintiffs in the litigation had developed cancer and “now want[ed] their money back,” Ms. Johns was asked if she thought people “should get their money back” to which Ms. Johns responded: “I don’t know anything about, you know, paying back, because I don’t get involved in those – that’s outside my responsibility.” Ex. 4, Johns Tr. 40:11-41:8. When pressed for her “*personal opinion*” on the matter she simply stated that “that’s general practice, I assume.” Ex. 4, Johns Tr. 41:13-18 (emphasis added). This is hardly Aurobindo agreeing that its VCDs were “worthless.”

*Second*, at Dr. Rao’s deposition, he, as a fact witness, was presented a counterfactual hypothetical. *See* Ex. 5, Rao Tr. 235:6-18, 235:23-236:4. Dr. Rao was asked to agree that Aurobindo’s VCDs containing “any amount of NDEA” would not be purchased by anyone. *See* Ex. 5, Rao Tr. 235:6-9. That premise is contrary to the facts of this case—such product was purchased, was not subject to recall because it was below the acceptable NDEA limit, and was available for continued use per FDA guidance. *See supra* Section IV.B. No credible argument can be made that Dr. Rao’s agreement to Plaintiffs’ counsel’s hypothetical proposition can be interpreted as Aurobindo agreeing that its VCDs were worthless. Notably, Plaintiffs exclude four lines from Dr. Rao’s transcript where he did *not* agree that Aurobindo’s VCDs were “valueless.” Mot., 10-11 (omitting Ex. 5, Rao Tr. 235:19-22 (“Q: It’s valueless? A: You know, the nitrosamine contamination, you know, cleared carcinogenic either after the long exposure.”))).

Neither the testimony from Ms. Johns nor the testimony from Dr. Rao limit Dr. Lambert’s own opinions regarding the value of Aurobindo’s products.<sup>7</sup> Moreover, Dr. Lambert, in his role as an expert witness, need not analyze and address every piece of evidence in a case. As the Court has reminded the parties

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<sup>7</sup> If Plaintiffs were genuine in their attack on Dr. Lambert’s opinion regarding the value of Aurobindo’s VCDs because he “is neither an economist . . . nor a medical doctor,” Mot., 9, they would not even entertain the testimony of Ms. Johns and Dr. Rao, who also are not economists or medical doctors.

already, perceived weakness in an expert's opinions can be exposed through "[v]igorous cross-examination" at trial; it is not grounds for exclusion. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

## V. CONCLUSION

There is no basis upon which to grant Plaintiffs' Motion. It must be denied.

Dated: June 2, 2022

Respectfully submitted,

By: /s/ John P. Lavelle, Jr.

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on June 2, 2022, I caused the foregoing to be electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ John P. Lavelle, Jr. \_\_\_\_\_